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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,307	10/16/2001	Ganapati R. Mauze	10003714	7843

7590 08/09/2004

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,307

Applicant(s)

MAUZE ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-13 and 21-43 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/13/04
10/16/01
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2004 has been entered.

Information Disclosure Statement

2. The references were clearly submitted, since a CD is in the application.

Claim Interpretation

3. Prior to examination, the claims must be analyzed, since claim construction precedes application of the statutory requirements for patentability.

In claim 21, as noted previously, the term "cartridge" carries no weight whatsoever, and anything may be a "cartridge".

The first paragraph of claim 21, with the "configured" and "designed" and "shaped" language, simply requires a component. There is no particular structural elements required by this paragraph whatsoever. The second paragraph requires that the "base element" component have a fluid entry port, the third paragraph requires a "fluid reservoir" and the fourth paragraph requires an "operator".

The language such as "configured to be inserted" or "designed to perform" or "shaped to define" all represent functional limitations in an apparatus. As MPEP 2114

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makes clear, "claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." No specific structure is required or imposed by the term "configured to be inserted into an instrument" other than that a sensor device of some sort can analyze the cartridge in some way.

However, where claims 34-43 require "fluid communication" between the sensor cartridge and the companion cartridge, this is a structural element which is not met by the previously cited prior art.

With regard to the issue of the relationship with the sensor cartridge and the companion cartridge, there is no requirement in the claims that these are physically separated, so an integrated device with both elements will anticipate these elements.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-23, 26-34, 36, and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent 5,856,174).

Lipshutz teaches a "cartridge" (see figure 3 and column 2, lines 15-43) and an analytical instrument (see figure 3) of claim 21 which comprises

A base element that can be inserted into an analysis device (see column 11, lines 48-52), where Lipshutz expressly teaches that the reaction chamber portion can

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be "mated with a reusable base unit (see column 26, lines 43-67)" which provides some elements.

Lipshutz further teaches the presence of an entry port (see column 16, lines 15-18, where an inlet port for the entire device is suggested),

A fluid reservoir (see column 26, lines 43-67 and see column 16, lines 18-20, where a "storage chamber" is discussed),

And where these are in fluid communication using a fluid transport system (column 2, line 23),

Where the cartridge performs an operation including a hybridization reaction chamber (see column 2, lines 26-28), or an amplification chamber used for PCR amplification (see column 2, lines 48-53 and column 6, lines 28-67).

As noted previously, Lipshutz teaches that the "cartridge" may be connected to a sensing "cartridge" either directly or indirectly (see column 11, lines 48-52) and is thereby shaped to interact with the remainder of a "diagnostic instrument".

With regard to claim 22, Lipshutz teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 12) as well as by a mechanical/electrical interface into a reader device (column 13, lines 25-35).

With regard to claims 23, Lipshutz teaches a reagent storage system in the cartridge (see column 16, lines 18-20).

With regard to claims 26-28, 36, 40, 42, 43, Lipshutz teaches thermocycling to perform PCR (see column 6, lines 28-67).

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With regard to claims 29, 32, 33, Lipshutz teaches fluid transport systems (see column 2, line 23, for example) (Claims 32 and 33 do not structurally delimit the device since no structural element is included which effects the process step of mixing).

With regard to claim 30, Lipshutz teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see column 2, lines 15-43).

With regard to claim 31, 38, 39, Lipshutz teaches a waste retrieval system (see figures 4A-C, where element 414 is the waste reservoir).

With regard to claim 34, Lipshutz teaches a device in which a sensor device and a companion cartridge are integrated on a single device in fluid communication with one another (see figure 3, for example).

With regard to claim 41, Lipshutz teaches lysis of cells for preparation of DNA (see column 5, lines 50-67).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 24, 25, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent 5,856,174) in view of Leiner et al (U.S. Patent 6,037,178).

Lipshutz teaches the limitations of claims 21-23, 26-34, 36, and 38-43 as discussed above. Lipshutz does not teach the use of calibration cartridges.

Leiner teaches the use of calibration cartridges (see abstract and column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a calibration cartridge as taught by Leiner with the device of Lipshutz since Liener states "It is an object of the present invention to propose methods of quality control and quality control liquids which will permit first a control measurement and then measurement of a specimen by means of one and the same single-use cartridge, in addition to providing information on the reliability of the analyzer, or rather, reliability and accuracy of the individual sensors contained in the single-use cartridge (see column 3, lines 45-51)." So an ordinary practitioner would have been motivated to include a calibration cartridge in order to improve the reliability and accuracy of the device.

Response to Arguments

9. Applicant's arguments filed April 13, 2004 have been fully considered but they are not persuasive.

Applicant correctly notes that the claim as amended distinguishes over the Sakata reference. Since the Andresen reference would be cumulative to Lipshutz in this context, only Lipshutz is applied. For the reasons noted above, Lipshutz remains applicable. Also, when Applicant argues that the Lipshutz reader device is not a "sensing cartridge", there is no structural difference that is imposed by the claim to distinguish the two elements. No structure is imposed by the "sensing cartridge" which differentiates it from the Lipshutz reader device. Further, as noted above, much of the other language cited is functional and imposes no distinct structure on Lipshutz. Finally, the "sensing cartridge" need not be physically separate from the "companion cartridge" so the integrated device of Lipshutz can include an integrated "sensing cartridge" which is in fluid communication with the "companion cartridge".


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
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